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Pay-to-Delay Settlements: The Circuit-Splitting Headache Plaguing Big Pharma

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Pay-to-Delay Settlements: The Circuit-Splitting Headache Plaguing Big Pharma

ABSTRACT

At its passage, the Hatch-Waxman Act was hailed as a much-needed step in making generic drugs more readily available to consumers, easing some of the heavy burdens placed on consumers by the necessary, but flawed, patent system that essentially granted brand-name pharmaceutical manufacturers a de facto economic monopoly over their drugs. One consequence of the Act, unforeseen by legislators and regulators, was the creation of a perverse incentive on behalf of pharmaceutical patent holders to pay alleged patent infringers substantial cash payments to delay entry into the particular drug market. These pay-to-delay settlements—or reverse-payment settlements—have been at the center of a prolific debate among economists, legal theorists, regulators, and various industry experts on the appropriate relationship between antitrust law and patent law. This troubling byproduct of the Hatch-Waxman Act has also slowly created a definitive split among the federal circuit courts over the past ten years. The conflict is now coming to a head as the Supreme Court reviews the legality of reverse-payment settlements in FTC v. Watson Pharmaceuticals. This Note recommends that the Court recognize that, by removing the patent validity testing from the courtroom to the settlement negotiation table, the patentee-plaintiffs also removed themselves from the protection against antitrust scrutiny that a patent provides. As such, certain evidence of reverse payments should give rise to a rebuttable presumption of an illegal restraint of trade, given its clear anticompetitive implications.

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Antitrust laws in general, and the Sherman Act in particular, are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms. And the freedom guaranteed each and every business, no matter how small, is the freedom to compete—to assert with vigor, imagination, devotion, and ingenuity whatever economic muscle it can muster.¹

– J. Marshall

One unintended byproduct of the Hatch-Waxman Act (Act) is the emergence of “reverse-payment” settlements—or “pay-to-delay” settlements—between brand-name-pharmaceutical manufacturers and generic-pharmaceutical manufacturers.² Under Hatch-Waxman, a generic manufacturer could win a patent challenge by establishing that the patent is invalid or not infringed by the generic company’s competing drug.³ If the generic manufacturer prevails, it stands to gain early entrance and a market duopoly with the patent owner in

1. United States v. Topco Assocs., Inc., 405 U.S. 596, 610 (1972) (Marshall, J.).

2. FED. TRADE COMM’N, PAY FOR DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 3 (2010), available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.

3. *Id.*

the market for the patented drug.⁴ Such a win could effectively “reallocate billions of dollars from producers to consumers[,]” because, by keeping lower-priced generic drugs off the market, drug companies are able to charge higher prices than they otherwise could.⁵ Reverse-payment settlements allow drug companies to maintain high prices by inducing resolution of patent infringement claims out of court.⁶ Essentially, the owner of the drug patent agrees to pay a generic drug manufacturer to refrain from marketing a competing version of the patented drug during the term of the patent as an alternative to challenging the patent via litigation.⁷

Reverse-payment settlements illustrate the quintessential conflict between patent law and antitrust law.⁸ While a patent license grants its owner wide latitude in protecting his monopoly entitlement, courts have developed antitrust law to reduce the negative effects of use of monopoly power.⁹ On the other hand, courts have traditionally interpreted such laws broadly, allowing significant discretion in application and enforcement.¹⁰ For reverse-payment settlements, the antitrust issue arises when two competing drug makers settle a patent suit before trial with a substantial cash payment from the patent holder to the generic manufacturer.¹¹ Such a transaction decreases competition by eliminating the possibility of earlier competition in that drug market, denying consumers the benefit of lower prices.¹² Importantly, it is the large cash payment *from the patent owner to the generic manufacturer*, not the litigation settlement in and of itself, that renders the transaction anticompetitive.¹³ This is because the payment allows the generic manufacturer a de facto share of the

4. *Id.*

5. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1558 (2006).

6. *See* FED. TRADE COMM’N, *supra* note 2, at 2.

7. *See id.*

8. *Cf.* Hemphill, *supra* note 5, at 1555–56 (summarizing the “stark” conflict between the means of antitrust law and those of patent law).

9. *See id.*

10. *See id.* at 1555 (“A law referred to as ‘the Magna Carta of free enterprise’ can hardly be expected to determine the results of particular cases.” (footnote omitted)).

11. *See id.* at 1557.

12. *See id.*

13. Professor Hemphill notes:

Privately optimal agreements that impose large negative effects upon nonparties frequently raise antitrust concerns. . . . Economic modeling has shown formally that settlements that include a cash payment from the patentee to the infringer provide consumers with less welfare, on average, than seeing the litigation to completion. The conclusion that this loss gives rise to an antitrust violation depends upon acceptance of the view, on which these models are premised, that consumers are entitled as a matter of antitrust law to the average benefits of litigation.

Id. at 1572–73 (footnotes omitted).

profits from the patented drug.¹⁴ Furthermore, these “sweetheart deals” are often accompanied by other concessions from the brand-name patent holder, such as granting the generic company an exclusive secondary license to sell the drug before the end of the patent term or agreeing to refrain from selling the drug after the patent expires, giving the generic company a brief monopoly.¹⁵ Such benefits compound the anticompetitive effects of reverse-payment settlements.¹⁶

The Federal Trade Commission (FTC) has strenuously opposed these pay-to-delay deals as anticompetitive and ultimately harmful for US consumers.¹⁷ And, due to the 2008 shift in administration and the subsequent shift in department leadership, the Antitrust Division at the US Department of Justice (DOJ), though it initially wavered in its stance toward pay-to-delay settlements, ultimately adopted a firm stance opposing pay-to-delay deals.¹⁸ The FTC continues to demonstrate its contempt for pay-to-delay deals by challenging the settlements in court, claiming restraint of commerce under the Federal Trade Commission Act.¹⁹ Courts have generally allowed drug

14. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 394 (2003) (“A hallmark of these anticompetitive agreements is that the patentholder agrees to share its monopoly profits with the challenger in order to induce the challenger to give up its fight. In the merger context this is clear: the challenger is paid the acquisition price. A *bald payment not to compete* is even more explicit (and more difficult to justify).” (emphasis added)).

15. See FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 25 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

16. *Cf. id.*

17. See FED. TRADE COMM’N, *supra* note 2, at 1–2. The FTC asserts that “[p]ay-for-delay” agreements are ‘win-win’ for the companies: brand-name pharmaceutical prices stay high, and the brand and generic share the benefits of the brand’s monopoly profits.” *Id.* at 1. But consumers will “miss out on generic prices that can be as much as 90 percent less than brand prices.” *Id.* The FTC recommends that “Congress should pass legislation to protect consumers from such anticompetitive agreements” because “[p]ay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices.” *Id.* at 2.

18. Brent Kendall, *DOJ Shifts Policy on Generic Drug Patent Settlements*, WALL ST. J. (July 6, 2009), <http://online.wsj.com/article/SB124691728092502381.html> (“In a public split between the agencies, the Justice Department under the Bush administration did not embrace the FTC’s viewpoint that the deals violated antitrust laws. The department’s change in position under the Obama administration goes a long way toward resolving that split.”). Subsequently, Christine Varney, Assistant Attorney General at the DOJ Antitrust Division, pledged the department’s full support of the FTC’s position against reverse-payment settlements. *Id.* She stated that “[Chairman Leibowitz] can count on the support of the Department of Justice as he goes forward and pursues [actions against reverse-payment settlements].” *Confirmation Hearings on Federal Appointments: Hearings Before the S. Comm. on the Judiciary*, 111th Cong. 758 (2009) (statement of Christine Varney, nominee for Assistant Attorney General, Antitrust Division, United States Department of Justice).

19. Many challenges resulted in settlement with the FTC. See, e.g., *In re Bristol-Myers Squibb Co.*, 135 F.T.C. 444 (2003) (outlining the BuSpar consent decree); *In re Hoechst Marion Roussel, Inc.*, No. 9293, 2001 WL 333643 (F.T.C. Apr. 2, 2001) (noting the Cardizem CD consent decree); *In re Abbott Labs.*, No. C-3945, 2000 WL 681848 (F.T.C. May 22, 2000) (discussing the

companies to settle a drug patent challenge, however, so long as the settlement does not keep the generic drug off the market beyond the patent's scheduled expiration.²⁰ Because settlements have not been shown to restrict competition beyond what the patent itself had insulated, courts have hesitated to apply antitrust analyses and instead have relied on the "scope of the patent" rule.²¹

On July 16, 2012, however, the US Court of Appeals for the Third Circuit explicitly declined to follow prior decisions from the Second, Eleventh, and Federal Circuits on the legality of reverse-payment settlements.²² Rejecting the use of the scope of the patent test, the Third Circuit employed the stricter quick-look "rule of reason" analysis to find that "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] prima facie evidence of an unreasonable restraint of trade."²³ This Third Circuit ruling created a circuit split with the Eleventh Circuit on the exact same patent infringement litigation settlement involving the Merck-owned patent for K-Dur.²⁴ Congress has remained silent on the issue, neglecting to restrict reverse-payment settlements by amending the Hatch-Waxman Act.²⁵

The recent circuit split and congressional inaction induced the US Supreme Court to grant certiorari to review the reverse-payment settlement issue. In December 2012, the Supreme Court granted cert in *FTC v. Watson Pharmaceuticals*, a pay-to-delay case where the Eleventh Circuit rejected the FTC's argument that pay-to-delay settlements violated antitrust laws and reaffirmed the use of the scope

Hytrin consent decree). In contrast, the brand-name manufacturer of the drug K-Dur and the first generic firm to file an ANDA together chose to litigate rather than settle with the FTC, and they won. See *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1058–62 (11th Cir. 2005).

20. Under the scope of the patent test, reverse-payment settlements are deemed permissible so long as (1) they do not exceed the scope of a patent, (2) the patent holder's patent infringement claim was not objectively baseless, and (3) the patent was not procured by fraud. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335–36 (Fed. Cir. 2008). Applying this test, three circuits have declined to invalidate patent litigation settlements so long as the delay of entry does not exceed the scope of the challenged patent. See *id.* (holding that the scope of the patent test applies, after analyzing the circuit split on the issue); see also *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005) (utilizing the scope of the patent test); *Schering-Plough Corp.*, 402 F.3d at 1076 (applying the scope of the patent test). But see *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (applying the rule of reason test to find the reverse-payment agreement at issue per se illegal).

21. E.g., *In re Ciprofloxacin Hydrochloride*, 544 F.3d at 1336; see cases cited and discussion *supra* note 20.

22. *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (3d Cir. 2012); see *infra* Part I.C.

23. *In re K-Dur*, 686 F.3d at 218.

24. *Id.* at 211–12.

25. See *infra* Part I.D.

of the patent test to determine the validity of pay-to-delay settlements.²⁶ A decision is expected by the end of June 2013.²⁷

This Note examines the history of reverse-payment settlements as well as antitrust and patent law principles to provide both judicial and extrajudicial solutions for the reverse-payment phenomenon. Part II provides a detailed background on reverse-payment settlements, including the regulatory scheme surrounding reverse-payment settlements, the FTC and DOJ viewpoints on the legality of reverse-payment settlements, congressional attempts to resolve the issue, and the key cases interpreting the legality of reverse-payment settlements. Part II also provides a detailed analysis of the judicial standards adopted by each of the federal courts of appeals reviewing reverse-payment cases and an analysis on the strengths and weakness of those approaches. Part III recommends that the Supreme Court adopt a hybrid approach that addresses the entitlement rights of patent law and consumer protection concerns of antitrust law. Part IV, however, asserts that congressional action will ease the tension between the two bodies of law and resolve the issue more effectively and comprehensively than judicial resolution. Part V concludes with a summary of potential solutions, highlighting the need for clarity and practicality when dealing with patents and antitrust concerns together.

I. BACKGROUND: THE HATCH-WAXMAN ACT AND ITS CONSEQUENCES

The enactment of the Hatch-Waxman Act was the impetus for the surge of reverse-payment settlements.²⁸ Since its inception, pharmaceutical patent holders and generic drug manufacturers have found a haven within which the parties can arrange a mutually beneficial financial arrangement where the generic drug manufacturer delays competing against the patent holder in production and sale of its drug for substantial payments.²⁹ Both of the federal antitrust enforcement agencies (DOJ and FTC) have taken a clear stance against the use of reverse-payment settlements by patent holders to

26. Jonathan Stempel, *U.S. Supreme Court to Hear 'Pay-for-Delay' Drug Case*, THOMSON REUTERS (Dec. 7, 2012), http://newsandinsight.thomsonreuters.com/Legal/News/2012/12_-_December/U_S_Supreme_Court_to_hear_pay-for-delay_drug_case.

27. *Id.*

28. FED. TRADE COMM'N, *supra* note 2; see also *Legislative and Regulatory Responses to the FTC Study on Barriers to Entry in the Pharmaceutical Marketplace: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 6 (2003) (statement of Daniel E. Troy, Chief Counsel, FDA); *id.* at 1 (statement of Sen. Orin Hatch, Chairman, S. Comm. on the Judiciary) ("[A]nticompetitive behaviors [were] made possible in part by the sometimes complex and admittedly confusing text of [the] law.").

29. See Hemphill, *supra* note 5, at 1557.

extend their market exclusivity and profit stream.³⁰ Many courts that have ruled on the issue have taken a different (oftentimes radically different) stance regarding the legality of such agreements.³¹ Furthermore, Congress has made multiple attempts, but ultimately has failed, to provide a legislative solution to the growing concern regarding the anticompetitive nature of such settlements.³²

A. The Regulatory Scheme: Hatch-Waxman Act

The Federal Food, Drug, and Cosmetic Act provides the regulatory framework under which pharmaceutical manufacturers must operate.³³ In order to sell a new drug, an applicant must undertake an extensive application process that includes multiple phases of clinical trial testing, substantial development costs, and a resource- and time-intensive review and approval process.³⁴ Because of this lengthy process, a patented drug may not even reach the market until after a considerable portion of its patent term already has expired.³⁵ Prior to the Hatch-Waxman Act, potential competitors had significant disincentives from participating in the New Drug Application (NDA) process required by the Federal Food, Drug, and Cosmetics Act³⁶ because they had low prospects of obtaining patent rents.³⁷ Furthermore, generic manufacturers were barred from developing a competing product that would be ready to market once the patent expired.³⁸

As a result of the competition-stifling regulatory scheme, Congress enacted the Hatch-Waxman Act to promote the availability of generic drugs in the pharmaceutical market and to incentivize

30. See *infra* Part I.B.

31. See *supra* note 20; *infra* Part I.C.

32. See *infra* Part I.D.

33. 21 U.S.C. § 355(a) (2006).

34. See, e.g., U.S. CONG. OFFICE OF TECH. ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS 1 (1993), available at <http://www.fas.org/ota/reports/9336.pdf> ("The full aftertax cost of [R&D for each new drug], compound[] to the[] value on the day of market approval, was roughly \$194 million (1990 dollars)."); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003) (estimating similarly calculated costs at \$802 million per drug).

35. See FED. TRADE COMM'N, *supra* note 15, at 4. See generally Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

36. 21 U.S.C. § 355(b).

37. See FED. TRADE COMM'N, *supra* note 2.

38. See 35 U.S.C. § 271 (explaining patent infringement); FED. TRADE COMM'N, *supra* note 15, at 4.

research and development of competing drugs.³⁹ Under the Act, a generic drug manufacturer can “piggyback” off of the patent owner’s NDA data by filing an Abbreviated New Drug Application (ANDA) and showing that its generic drug is a “bioequivalent” to the patented drug.⁴⁰ These provisions can significantly reduce the amount of time and resources required to obtain FDA approval.⁴¹

More important to the issue of reverse payments, the Act provides generic drug competitors incentives to challenge existing drug patents before they expire.⁴² Under the Act, an ANDA applicant can file a “Paragraph IV” certification where the applicant asserts that the patent it is challenging is either invalid or would not be infringed by its version of the drug.⁴³ Upon receipt of the Paragraph IV certification, the patent owner has forty-five days in which to file a patent infringement suit against the Paragraph IV filer.⁴⁴ Because the Paragraph IV filer is protected from infringement liability so long as it has not begun marketing the drug, however, the generic drug manufacturer’s risk profile is completely inverted.⁴⁵ It now stands to lose very little by challenging the patent.⁴⁶

39. FED. TRADE COMM’N, *supra* note 15, at 4. The Hatch-Waxman Act was passed as the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b–68c, 70b (2006); 21 U.S.C. §§ 301–360 (2006); 28 U.S.C. § 2201 (2006); 35 U.S.C. §§ 156, 271, 282 (2006)).

40. *See* 21 U.S.C. § 355(j)(2)(A)(iv).

41. *See* C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 617–18 (2011) (estimating the cost of preparing and filing an ANDA to be \$1 million).

42. *See id.* at 618.

43. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This is referred to as a “Paragraph IV” certification because it falls under the fourth paragraph of the relevant statutory section. The ANDA filer also can elect to file under paragraphs I–III, which entail a certification that the branded manufacturer failed to file the required “Orange Book” listing of the patent, the patent has expired, or approval is being sought effective on a date after patent expiration. *See id.* § 355(j)(2)(A)(vii)(I)–(III). In fact, most ANDA filers do not elect to file under Paragraph IV. *See* Hemphill & Sampat, *supra* note 41, at 618.

44. 21 U.S.C. § 355(c)(3)(C).

45. Note that the Paragraph IV filer faces minimal liability for infringement if the filer does not market the product because there generally are no damages if the product was never sold. *See* Emily Michiko Morris, *The Myth of Generic Pharmaceutical Competition Under the Hatch-Waxman Act*, 22 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 245, 264 (2012). Once the infringement litigation is initiated by the patent owner, the patent owner stands to lose much—its patent. But because the filer has not yet marketed the product, the generic manufacturer stands to gain significantly from the litigation—the prospect of marketing its generic version of the patented drug (due to a noninfringement or invalidity verdict) plus a 180-day exclusive license to sell the generic drug. *See id.* If the patent owner does not initiate an infringement suit within forty-five days of the ANDA grant, the filer is then free to market the drug without fear of liability for infringement damages. *See* 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV), (j)(5)(B)(iii)(IV)(iv)(I); 35 U.S.C. § 271(e)(1).

46. *See* discussion *supra* note 45.

In fact, the first filer of a Paragraph IV certification against a particular patented drug stands to receive a 180-day period of market exclusivity should the application succeed—a sort of reward or incentive for being the first challenger to a pharmaceutical patent.⁴⁷ This presents another opportunity for generic manufacturers to receive a significant windfall from settling their infringement dispute with the patentee.⁴⁸ The 180-day exclusivity period begins to run when the first challenger's generic drug enters the market.⁴⁹ Therefore, as part of the settlement, generic companies may agree to refrain from entering the market and “park” their exclusivity in exchange for monetary consideration, not only preventing themselves but also *other* generic manufacturers from entering the market.⁵⁰

B. The Enforcement Agencies: The FTC and DOJ Weigh In

Historically, the FTC's Competition Bureau and the Antitrust Division at the DOJ have espoused conflicting stances on the legality of reverse-payment settlements.⁵¹ The FTC consistently and strenuously opposes reverse-payment settlements as an anticompetitive practice and engaged in multiple lawsuits and other enforcement actions to invalidate such agreements.⁵² The FTC insists that “[p]ay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices.”⁵³

The DOJ, on the other hand, initially blessed reverse-payment transactions as the patent holder's legitimate enforcement of its rights.⁵⁴ Under the Bush administration, the DOJ refused to join the

47. 21 U.S.C. § 355(j)(5)(B)(iii)(IV)(iv)(I).

48. See Morris, *supra* note 45, at 272.

49. 21 U.S.C. § 355(j)(5)(B)(iii)(IV)(iv)(I).

50. The first generic competitor to file an ANDA is given a 180-day exclusivity period during which no other generic manufacturer may market an equivalent generic drug. See *id.* § 355(j)(5). However, the exclusivity period does not begin to toll until the filer *actually begins to market the drug*, or a judicial finding of patent invalidity or noninfringement, nor does the exclusivity grant expire, once granted. See *id.* This allows an ANDA filer to “park” its exclusivity power to prevent other generic manufacturers from also challenging the same patent through the same process. See Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1755 (2003). This creates an incentive for both the generic manufacturer and the patent holder to settle its infringement litigation with payment for the generic manufacturer's delay of entry, which would prevent the start of the 180-day exclusivity period and block other generics from the market until the patent expires or they choose to obtain FDA approval through the traditional NDA process, which is effectively cost prohibitive. See *id.*

51. See *supra* notes 17–18.

52. See FED. TRADE COMM'N, *supra* note 2, at 1–2.

53. *Id.* at 2.

54. Brief for the United States as Amicus Curiae at 8–9, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273); Kendall, *supra* note 18.

FTC in its enforcement actions against these agreements.⁵⁵ To illustrate, the DOJ filed an amicus brief in *Schering-Plough Corp. v. FTC*, where it stated that “a settlement involving restrictions on the sale of the products in question is not necessarily impermissible” when dealing with patents because there are competing policy concerns.⁵⁶ The DOJ urged that the court must strike a balance between the right to exclude granted by the patent and the Hatch-Waxman goal of facilitating challenges to weak patents, but it did not advance a standard by which the court should decide.⁵⁷

However, with the change in administration, both at the White House and within the leadership structure in the Antitrust Division, the DOJ began to take a less friendly view toward reverse-payment settlements, though still more equivocal in its stance than its antitrust enforcement counterpart, the FTC.⁵⁸ At the invitation of the Second Circuit, the DOJ filed an amicus brief in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, where it articulated its new stance.⁵⁹ In its brief, the DOJ asserted that “[t]he anticompetitive potential of reverse payments . . . is sufficiently clear that such agreements should be treated as presumptively unlawful under Section 1 of the Sherman Act.”⁶⁰ The DOJ added that “[l]iability properly turns on whether, in avoiding the prospect of invalidation that accompanies infringement litigation, the parties have by contract obtained more exclusion than warranted in light of that prospect.”⁶¹ It added an important caveat: that the parties may defeat the presumption of unlawfulness if the payment afforded in the agreement does not exceed estimated litigation costs.⁶² Because the DOJ believes that private parties’ right to contract should be respected when developing a policy regarding reverse-payment settlements, it generally advocates broader exceptions to the presumption of illegality.⁶³

55. See Kendall, *supra* note 18.

56. Brief for the United States as Amicus Curiae at 8, *Schering-Plough Corp.*, 548 U.S. 919 (No. 05-273).

57. See *id.* at 10–11.

58. See Kendall, *supra* note 18.

59. Brief for the United States in Response to the Court’s Invitation at 9–10, *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010) (Nos. 05-2851-cv(L), 05-2852-cv(CON), 05-2863-cv(CON)).

60. *Id.* at 10.

61. *Id.* at 25.

62. *Id.* at 28.

63. *Id.* at 19–21, 27–32.

C. The Case Law: Reverse Payments on the Continuum of Legality

The case law regarding reverse-payment settlements is definitively split on the balance between patent rights and antitrust concerns.⁶⁴ This stark difference is illustrated in the contradictory stances taken by the Third Circuit and the Eleventh Circuit on the same reverse-payment settlement for the same drug patent, K-Dur. Three other courts of appeals—the Second, Sixth, and Federal Circuits—have ruled on the issue, also splitting on the balance between the interests of the patent holder and the value of antitrust enforcement.

1. The K-Dur Litigation: A Tale of Two Circuits

The litigation over the K-Dur patent settlement represents a rarity—a circuit split between two different courts of appeals over a single case or transaction.⁶⁵ In a private antitrust enforcement suit, a group of wholesale and retail buyers of K-Dur, a blood pressure medication, filed an antitrust lawsuit against Merck, the owners of the K-Dur patent.⁶⁶ The challengers argued that the settlement terms entered into by Merck and generic manufacturers of K-Dur violated Section 1 of the Sherman Antitrust Act, which outlaws unreasonable restraints on trade.⁶⁷ The agreement provided that, without conceding “the validity, infringement, or enforceability of the ’743 patent, [the generic manufacturer] would refrain from marketing its generic potassium chloride supplement or any similar product” in exchange for a cash payment of \$60 million over three years from the patent holder, Schering.⁶⁸ The US District Court for the District of New Jersey ruled against the plaintiffs, using the scope of the patent test.⁶⁹ The plaintiffs appealed, and the Third Circuit held on appeal that any payment to a generic challenger who had agreed to delay entry into the market was “*prima facie* evidence of an unreasonable restraint of trade.”⁷⁰ To overcome this presumption, the patent owner must then prove that the deal was for a purpose other than postponing market

64. See *infra* Part I.C.

65. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005).

66. *In re K-Dur*, 686 F.3d at 202, 203 n.2.

67. See *id.* at 206–09.

68. *Id.* at 205.

69. See *id.* at 208, 214; see *supra* note 20 and accompanying text (discussing the scope of the patent test parameters).

70. *In re K-Dur*, 686 F.3d at 218.

entry or that it offered some procompetitive benefit to compensate for the anticompetitive effect of the delay.⁷¹

The Third Circuit's decision represents a major departure from established precedent in the Second, Eleventh, and Federal Circuits allowing such transactions.⁷² The Third Circuit decision varied most from the Eleventh Circuit, which found in *Schering-Plough Corp. v. FTC* that the exact same settlement at issue in the Third Circuit decision was allowable under the scope of the patent test.⁷³ The *Schering-Plough* court rejected the FTC ruling that stated that any settlement in which "the generic receives anything of value and agrees to defer its own research, development, production or sales activities" is an unlawful restraint of trade.⁷⁴ Instead, the court reasoned that neither the rule of reason nor per se analysis applied for an agreement involved a patent, so long as the agreement remained within the patent's scope.⁷⁵ The court reasoned that "[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition," and therefore the anticompetitive nature is present by force of law.⁷⁶ Instead of the traditional antitrust analysis, the court created and applied a new test that "requires an examination of: (1) the scope of the exclusionary potential of the patent, (2) the extent to which the agreements exceed that scope, and (3) the resulting anticompetitive effects."⁷⁷ Applying this test to the reverse-payment settlements for the K-Dur drug, the court found that the settlement agreements had no improper anticompetitive effect.⁷⁸

Merck filed a petition for a writ of certiorari at the Supreme Court.⁷⁹ Further increasing the likelihood of Supreme Court review, just two days after the Third Circuit delivered its game-changing opinion, the Eleventh Circuit denied rehearing en banc to the dismissal of the FTC's challenge to reverse-payment settlement in *FTC v. Watson Pharmaceuticals*.⁸⁰ This provided the FTC the incentive to petition for certiorari in *Watson*, especially since the FTC is now armed with the Third Circuit's *K-Dur* decision invalidating

71. See *id.*

72. See *id.* at 211–14.

73. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1075–76 (11th Cir. 2005).

74. *Id.* at 1062, 1065–66.

75. *Id.*

76. *Id.* at 1065–66.

77. *Id.* at 1066.

78. See *id.* at 1068, 1076.

79. Petition for a Writ of Certiorari, *Merck & Co. v. La. Wholesale Drug Co.*, No. 12-245 (U.S. Aug. 24, 2012), 2012 WL 3645102.

80. *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1303–05, 1315 (11th Cir.), *cert. granted sub nom.*, *FTC v. Actavis*, 133 S. Ct. 787 (Dec. 7, 2012) (No. 12-416).

reverse-payment settlements as anticompetitive. In December 2012, the Supreme Court agreed to hear *FTC v. Watson Pharmaceuticals*.⁸¹

2. Sixth Circuit: Per Se Illegal Restraints on Trade

In *In re Cardizem CD Antitrust Litigation*, the Sixth Circuit ruled that reverse-payment settlements are per se unlawful because they are unreasonable restraints on trade.⁸² In this case, a generic manufacturer, Andrx, refrained from marketing a generic version of the drug in question, after it received ANDA approval, in exchange for annual \$40 million payments from the patent holder during the delay.⁸³ After one year, the parties settled the infringement claim against Andrx whereby Andrx received \$89.83 million.⁸⁴ On June 23, 1999, a full year after Andrx could have marketed its generic drug on the open market, Andrx finally released its version of the Cardizem Drug, Cartia XT.⁸⁵ In other words, Andrx was paid to delay generic entry while the litigation was pending and, as a bonus, was not forced to sacrifice the Hatch-Waxman exclusivity period it received with its ANDA application once the litigation terminated.⁸⁶

Indirect consumers and other putative class representatives challenged the agreements on antitrust grounds.⁸⁷ The case reached the Sixth Circuit on interlocutory appeal from the district court's grant of summary judgment finding that the interim agreement was a per se illegal restraint of trade.⁸⁸ The Sixth Circuit emphatically agreed, stating that "there is simply no escaping the conclusion that the Agreement . . . was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a per se illegal restraint of trade."⁸⁹ The court further noted that "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor \$40 million per year to stay out of the market."⁹⁰ HMR argued that Andrx would have remained out of the market even without the settlement

81. Stempel, *supra* note 26.
82. 332 F.3d 896, 908–09 (6th Cir. 2003).
83. *Id.* at 902.
84. *Id.* at 903.
85. *Id.*
86. *See id.* at 901–03.
87. *Id.* at 900.
88. *Id.* at 905.
89. *Id.* at 908.
90. *Id.* (footnote omitted).

for fear of damages from the pending patent infringement litigation.⁹¹ The court rejected this notion, reasoning that "had HMR been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid \$89 million to effect what the patent and infringement suit had already accomplished."⁹² Therefore, the court saw no reason for the agreement other than reducing competition.⁹³

3. Second, Eleventh, and Federal Circuits: Lawful Per Scope of the Patent Test

In *In re Tamoxifen Citrate Antitrust Litigation*, the Second Circuit rejected the Sixth Circuit's and the FTC's per se rule and held that reverse-payment settlements do not violate antitrust laws where they fall within the exclusionary zone of the patent.⁹⁴ In other words, the Second Circuit adopted the scope of the patent test.⁹⁵ This case involved a reverse-payment settlement in the patent infringement case over Tamoxifen, a cancer drug.⁹⁶ Barr Laboratories, the generic manufacturer, agreed to delay marketing its generic drug until after the expiration of Zeneca, Inc.'s patent on Tamoxifen in exchange for \$66 million in cash payments to Barr and its supplier, as well as a nonexclusive license to sell its off-brand drug.⁹⁷ The parties also agreed to move to vacate the district court's judgment.⁹⁸

Various consumers and consumer groups challenged the settlement on antitrust and other grounds.⁹⁹ The district court rejected the plaintiff's challenges to the settlement and granted the defendant's motion to dismiss.¹⁰⁰ On appeal, the Second Circuit affirmed the district court's ruling, underscoring a long-standing policy in favor of settlement, including in patent and other intellectual property cases.¹⁰¹ The court stated that disallowing settlements may "heighten the uncertainty surrounding patents and might delay innovation."¹⁰² Further, the court rejected the notion that settlements allow weak patents to wrongfully survive litigation, while noting that

91. *Id.* at 915.

92. *Id.*

93. *See id.*

94. 466 F.3d 187, 213–14 (2d Cir. 2005).

95. *See id.* at 213.

96. *Id.* at 190.

97. *See id.* at 193–94.

98. *Id.* at 194.

99. *Id.* at 196.

100. *Id.* at 197.

101. *Id.* at 202–03, 221.

102. *Id.* at 203.

it would be impossible and improper for the court to engage in an ex post analysis of how “the judicial system will lead to any particular result in [a] case.”¹⁰³

Furthermore, the court “decline[d] to conclude . . . that reverse payments are per se violations of the Sherman Act,” particularly in light of its acceptance of the assertion that “reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them.”¹⁰⁴ The court also rejected the plaintiff’s argument that the fact that the reverse payments seem to far exceed the actual value of the generic drug automatically makes the transaction an illegal restraint on trade.¹⁰⁵ The court stated that “so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.”¹⁰⁶ Though the court admits that this policy may allow some additional protection for weak patents, it took solace in its assumption that the weakest and least deserving of patents would be attacked by multiple would-be generic entrants and therefore would be unable and unwilling to buy out every potential rival.¹⁰⁷

Finally, the court held that the terms of the settlement did not unlawfully exceed the scope of the Tamoxifen patent.¹⁰⁸ Because the settlement permitted other generic manufacturers to challenge the patent and did not restrict access to unrelated or noninfringing products, the court found that the settlement was actually well within the confines of the monopoly rights presumptively granted to the patent owner.¹⁰⁹ Importantly, the court distinguished the Sixth Circuit’s Cardizem agreement from the Tamoxifen agreement, averring that the Cardizem agreement was much more restrictive.¹¹⁰

The Eleventh Circuit continued the trend of favoring patent rights over antitrust concerns in *FTC v. Watson Pharmaceuticals*.¹¹¹ The Eleventh Circuit rejected the FTC’s case against Solvay Pharmaceuticals and generic manufacturers Watson Pharmaceuticals,

103. *Id.* (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 159–60 (1990)).

104. *Id.* at 206.

105. *See id.* at 208–09.

106. *Id.*

107. *See id.* at 211.

108. *Id.* at 213.

109. *Id.* at 214–15.

110. *See id.* at 215.

111. *See FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1303–05 (11th Cir.), *cert. granted*, 133 S. Ct. 787 (Dec. 7, 2012) (No. 12-416).

Par Pharmaceuticals, and Paddock Laboratories over the parties' reverse-payment settlement agreement related to patents for AndroGel—a testosterone replacement drug.¹¹² Here, the reverse-payment settlement included the following terms: (1) Solvay pays Par and Paddock \$10 million per year for six years, (2) Solvay pays Par and Paddock an additional \$2 million per year for the backup manufacturing assistance, and (3) Solvay shares some of its AndroGel profits with Watson.¹¹³ The profit share payments were estimated to be between \$19 million and \$30 million per year.¹¹⁴

The court found that the agreement was legal, reaffirming Eleventh Circuit precedent of using the scope of the patent test.¹¹⁵ The court noted that “absent sham litigation or fraud in obtaining the patent, a reverse-payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.”¹¹⁶ The court rejected the FTC's argument that the underlying patent had no exclusionary potential because Solvay was not likely to prevail in the underlying infringement claim against the generic companies, and therefore any reverse payment that excluded competition from the market necessarily exceeded the potential exclusionary scope of the patent.¹¹⁷ The court wanted to avoid “deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task.”¹¹⁸ The court also soundly rejected the FTC's fears regarding the significant anticompetitive harms and misuse of both the patent system and judicial system caused by the scope of the patent test; if the patent is truly invalid, other generic manufacturers would have incentive to jump into the fray because the patent holder would be unlikely to share its profits with every challenger.¹¹⁹

In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, the Federal Circuit ruled that the reverse payments being challenged did not exceed the scope of the patent and therefore were presumptively lawful.¹²⁰ This case involved a reverse-payment settlement in the patent infringement case over Ciprofloxacin (Cipro), a type of antibacterial medication.¹²¹ Barr, the generic manufacturer, agreed to

112. *Id.*

113. *Id.* at 1305.

114. *Id.*

115. *Id.* at 1312.

116. *Id.*

117. *Id.* at 1312–13.

118. *Id.* at 1315.

119. *Id.*

120. 544 F.3d 1323, 1333 (Fed. Cir. 2008).

121. *Id.* at 1327–28.

delay marketing its generic drug until six months prior to the expiration of Bayer AG's patent on Tamoxifen in exchange for \$49 million up front and either a supply of Cipro for resale or an additional \$300 million in cash over seven years.¹²²

Cipro consumers and consumer groups challenged the settlement on antitrust and other grounds.¹²³ The district court granted summary judgment for the defendants, and the Federal Circuit affirmed.¹²⁴ The court concurred that the agreement was legal because the agreement did not exceed the scope of the patent or, as described by the court, the "exclusionary zone" of the patent.¹²⁵ The court reasoned that the agreement was merely meant to exclude Barr from engaging in market activity that violates Bayer's sanctioned monopoly rights as the patentee of Cipro.¹²⁶ The court further noted that public policy favors settlement, and that settlements of patent infringement suits are commonplace and well accepted within the patent framework.¹²⁷

Finally, the Federal Circuit, like the Second Circuit, distinguished the agreement at hand from the Cardizem settlement.¹²⁸ The court noted that the Cardizem settlement required the generic manufacturer to refrain from manufacturing unrelated drugs, a requirement which was outside of the patent's "exclusionary zone."¹²⁹ Though the court did not directly acknowledge that restrictions on the generic manufacturers that are unrelated to the maintenance of the patent rights would be per se illegal, it did suggest that their analysis might differ under different circumstances.¹³⁰ In sum, while each of the three courts of appeals grappled with slightly variant forms of reverse-payment settlements with varying anticompetitive effects, the courts all found such agreements lawful because the anticompetitive effects ostensibly played no role in their analyses.¹³¹ Rather, these courts narrowed their review to ensure that the patent was not illegally extended through the agreements.¹³²

122. *Id.* at 1329 n.5.

123. *Id.* at 1329.

124. *Id.* at 1340.

125. *Id.* at 1333.

126. *Id.*

127. *Id.*

128. *See id.* at 1335.

129. *Id.*

130. *See id.*

131. *See supra* Part I.C.3.

132. *See supra* Part I.C.3.

D. Legislative Response: Congressional Silence and Failure to Regulate

On February 9, 2012, Congress attempted to prevent reverse-payment settlements in Hatch-Waxman lawsuits.¹³³ Congressman Waxman and Congressman Rush introduced Protecting Consumer Access to Generic Drugs Act of 2012 (H.R. 3995) “[t]o prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes.”¹³⁴

The bill prohibits reverse-payment settlements, defined as agreements “resolving or settling a patent infringement claim” in which an ANDA filer “receives anything of value.”¹³⁵ The ANDA filer agrees “not to research, develop, manufacture, market, or sell, for any period of time, the drug” that is the subject of the ANDA and the patent infringement lawsuit.¹³⁶ The bill makes an exception for settlements where the only “value” received by the ANDA filer is the ability to market the drug before expiration of the patents in the infringement lawsuit or before expiration of “any other statutory exclusivity that would prevent the marketing of such drug.”¹³⁷

Like its (failed) predecessors, H.R. 3995 specifies that violations of its provisions will fall within the FTC’s purview rather than under the Sherman Act as an agreement in restraint of trade.¹³⁸ This portion of the bill states that such an agreement will be considered “an unfair and deceptive act or practice and an unfair method of competition in or affecting interstate commerce” under Section 5 of the Federal Trade Commission Act.¹³⁹ The FTC is given full rulemaking authority to implement these enforcement provisions and the power to exempt agreements on a case-by-case basis that it finds “to be in furtherance of market competition and for the benefit of consumers.”¹⁴⁰ The bill also provides that an ANDA filer found to be in violation of the reverse-payment provisions shall forfeit the 180-day exclusivity period and that all agreements shall be filed with the DOJ and the FTC.¹⁴¹

133. Protecting Consumer Access to Generic Drugs Act of 2012, H.R. 3995, 112th Cong. (2012).

134. *Id.*

135. *Id.* § 2(a).

136. *Id.* § 2(a)(2).

137. *Id.* § 2(b).

138. *Id.* § 2(c).

139. *Id.*

140. *Id.* § 3.

141. *Id.* § 4.

This bill does not differ significantly from past failed attempts to regulate reverse payment and therefore is vulnerable to the same critiques, particularly regarding the effect on generic manufacturers and the significantly reduced incentives to file ANDA challenges under Hatch-Waxman.¹⁴² Generic applicants would need to consider whether challenging branded drugs would be “worth it,” given that they might have to choose between litigating to the bitter end or be forced to satisfy the FTC’s concerns with any settlement they contemplate.¹⁴³ Furthermore, because of the wide discretion that would be granted to the FTC in enforcing the Act, its “concerns” may be quite difficult to predict.¹⁴⁴

II. ANALYSIS: JUDICIAL PHILOSOPHIES AT WAR

An agreement between competitors to divide markets or allocate customers is per se illegal because “such agreements preclude competition not only in pricing, but also with respect to quality, service and other competitive stimuli.”¹⁴⁵ A reverse-payment settlement is, at its core, a market division that allocates customers along a temporal axis (as opposed to traditional geological boundaries). And even if reverse-payment settlements are not classified as market allocation schemes and therefore not subject to per se illegality treatment, such agreements are unreasonable restraints on trade because there is not a plausible net procompetitive effect from the transaction, and it is therefore subject to antitrust action.¹⁴⁶

Because the agreement is made in the context of a patent infringement settlement, however, courts have protected such agreements under a blanket of legitimacy in patent law.¹⁴⁷ But while a patentee has a right to exclude its competitors from marketing its patented product, their right to exclude can only be enforced by bringing a patent infringement suit against the alleged infringer. A reverse-payment settlement is essentially a patentee using corporate

142. Note that H.R. 3995 was a reintroduction of H.R. 1706, 111th Cong. (1st Sess. 2009), which was a reintroduction of H.R. 1902, 110th Cong. (1st Sess. 2007). Other failed attempts to amend the Federal Food, Drug, and Cosmetics Act to address the issue of pay-to-delay settlements include (but are not limited to) Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (1st Sess. 2009) and Drug Price Competition Act of 2009, S. 1315, 111th Cong. (2009). For the sake of clarity and efficiency, the Author’s analysis will focus on H.R. 3995.

143. See H.R. 3995 §§ 2(c), 3 (2012).

144. See *id.* §§ 2–3.

145. See 1 LOUIS ALTMAN & MALLA POLLACK, CALLMANN ON UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES § 4:35 (4th ed. 2012).

146. See *id.* § 4:37.

147. See *supra* Part I.C.3.

funds to maintain its right to exclude, not the judicial system established to both test and protect patents.¹⁴⁸

A. Reverse-Payment Settlements as Market Allocation

Any agreement where competitors agree not to compete for certain territories or certain customers is assumed to be harmful to competition and can only be motivated by the intent to eliminate competition.¹⁴⁹ Therefore, the Supreme Court has ruled that such agreements are per se illegal.¹⁵⁰ Agreements that are considered per

148. The reverse-payment settlement, rather than serving as a legitimate product of weighing the risks each party faces should the case move to trial, is merely a cover for an inappropriate splitting of corporate profits gleaned from monopoly rents. Therefore, the settlement actually undermines the role of the judiciary in determining whether a patent should be given legal force. Patents are meant to be a *shield* to protect innovators from blatant misappropriation of their inventions. See CRAIG A. NARD, *THE LAW OF PATENTS* 437 (Vicki Been et al. eds., 2d ed. 2011). The natural consequence of exercising the right to exclude is that the patent's validity is tested in the courtroom; the shield should only be as strong as the patent itself. See *id.* at 439.

The incentives driving reverse-payment settlements are almost unique to pharmaceutical patents. This is because a grant of a pharmaceutical patent gives the patentee both *legal* and *economic* monopoly power. See *id.* at 2; DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 101 (2009). Legal monopoly power, the ability to be the only player to market a specific invention, comes with every patent. See NARD, *supra*, at 2. However, because most markets have a plethora of substitutes that can effectively compete with the patent holder and despite holding legal monopoly power, most patent holders do not have an economic monopoly. See *id.* at 2. Pharmaceuticals are unique because of the inherent lack of substitutes in the market. See BURK & LEMLEY, *supra*, at 101. In fact, when a new drug is introduced, it may create an entirely new market. See *id.* Therefore, when a patentee is granted a pharmaceutical patent, in many cases this will also give them a de facto economic monopoly. In taking a practical view of the patent holder's risk-benefit analysis, it is easy to see—given the enormity of uncertainty that comes with actual litigation and the potential that the patent was wrongfully granted given the weaknesses in the current patent-review process—why a patent holder would agree to make such large payments to a patent challenger in the case of pharmaceutical patents.

Pharmaceutical patent holders engaging in reverse-payment settlements are effectively using their patents as a *sword*, because they are able to pay potential challengers to remain out of the market using the corporate profits earned by that patent—a patent that may not be valid. The use of this kind of sword is uniquely available where having a patent produces both a legal and economic monopoly, and the demand for the product is inelastic enough to produce significant monopoly rents. Here, the patent holder refuses to use its shield by using its monopoly rents—which are essentially excess corporate profits—to ward off its patent's challengers. This is particularly effective within the Hatch-Waxman scheme because of the ANDA filer's ability to “park” its grant and prevent other challengers from also using the ANDA system to challenge the patent holder. See *supra* note 50 and accompanying text.

For further discussion on the potential for patent exceptionalism in pharmaceutical patents, see Hemphill, *supra* note 5, at 1597–604.

149. Hemphill, *supra* note 5, at 1597–604.

150. The Court reaffirmed that:

One of the classic examples of a per se violation of § 1 is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition. . . . This Court has reiterated time and time again that “[h]orizontal territorial limitations . . . are naked restraints of trade with no purpose

se illegal are taken out of the realm of rule of reason analysis because history has emphatically demonstrated that the particular category of transactions have a “pernicious effect on competition and lack of any redeeming virtue.”¹⁵¹

Traditionally, firms have allocated markets across geographical boundaries. For instance, in *United States v. Sealy, Inc.*, Sealy made agreements with its licensees not to license other manufacturers or retailers to sell Sealy products in the licensee’s assigned territory in exchange for the licensee’s agreement to sell only within that territory. The Supreme Court held that this agreement was a horizontal territorial restraint of trade, which is a per se violation of Section 1 of the Sherman Act.¹⁵²

A reverse-payment settlement is essentially an absolute and unequivocal market allocation of the entire United States for a specified period of time.¹⁵³ Market allocation occurs when competitors agree not to compete with each other in particular geographic markets, for particular customers, or within particular product lines.¹⁵⁴ By allocating markets, competitors effectively “insulate themselves from competition through collusion.”¹⁵⁵ Therefore, courts have determined that horizontal market allocations are per se illegal because “[h]orizontal territorial limitations . . . are naked restraints of

except stifling of competition.” Such limitations are per se violations of the Sherman Act.

United States v. Topco Assocs., Inc., 405 U.S. 596, 606–09 (1972) (citations omitted); *see also* *Addyston Pipe & Steel Co. v. United States*, 175 U.S. 211, 237 (1899).

151. Justice Black outlined the Court’s reasoning for adopting a per se approach for certain transactions and business relationships. The Court found that:

[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use. This principle of per se unreasonableness not only makes the type of restraints which are proscribed by the Sherman Act more certain to the benefit of everyone concerned, but it also avoids the necessity for an incredibly complicated and prolonged economic investigation into the entire history of the industry involved, as well as related industries, in an effort to determine at large whether a particular restraint has been unreasonable—an inquiry so often wholly fruitless when undertaken.

N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958).

152. *United States v. Sealy, Inc.*, 388 U.S. 350, 357 (1967).

153. *See* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 72 (2009).

154. ANDREW I. GAVIL, ET AL., *ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS AND PROBLEMS IN COMPETITION POLICY* 128 (2d ed. 2008). A market allocation scheme “could not effectively convey power over price unless the parties to the arrangement collectively possess market power.” *Id.* This Note assumes that the patent holder and the ANDA challenger has the requisite market power because of the de facto economic monopoly that often accompanies a pharmaceutical patent.

155. *Id.*

trade with no purpose except stifling competition.”¹⁵⁶ Although these agreements do not divide the United States or world markets into multiple geographic territories as in the archetypal market allocation case, an allocation of 100 percent is no less an allocation than, say, 10, 35, or 60 percent. A court should not exclude a division of market based on time from per se treatment merely because of the temporal nature of the split. There is still a geographic dimension (a market allocation of 100 percent of the entire United States), and the demarcation based on time creates the same harmful effect on competition.¹⁵⁷

The Sixth Circuit decided in *Cardizem* to consider a reverse-payment settlement as a per se illegal market allocation agreement, where the patent holder agreed to make large compensatory payments to the generic manufacturer in return for its agreement to delay marketing its generic drug prior to the outcome of patent litigation between the parties.¹⁵⁸ The settlement parties’ argument that the agreement was merely ancillary to protecting the patent holder’s rights was rejected as a matter of law because the arrangement extended to all generic versions of the drug, regardless of whether or not the drug actually infringed the patent.¹⁵⁹ Still, one common argument against the general application of the *Cardizem* rationale to other reverse-payment cases is that the particular settlement in that case required the generic manufacturer to “park” its generic exclusivity right granted through the ANDA process.¹⁶⁰

156. *White Motor Co. v. United States*, 372 U. S. 253, 263 (1963).

157. *See id.*

158. *See supra* Part II.C.2.

159. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908–09 (6th Cir. 2003). This lawsuit developed from an attempt by a generic drug manufacturer, Andrx, to obtain FDA approval of a generic version of Cardizem, the patent of which was held by Hoechst AG. 1 WILLIAM C. HOLMES, INTELLECTUAL PROPERTY AND ANTITRUST LAW § 5:5 (2013). Andrx filed its ANDA to market the generic brand and Hoechst filed a patent infringement suit against Andrx. *Id.* The suit triggered the statutory thirty-month stay on FDA approval of the generic brand to give the court time to review the suit. *Id.* While the patent infringement suit was pending, the FDA granted Andrx a provisional approval to market its drug. *Id.* This meant that because Andrx was the first company to apply for generic marketing rights, it was granted a 180-day exclusivity to market a generic drug alternative to Cardizem, should the court decide that the Cardizem patent was not infringed by the generic version or was invalid. *Id.* After the FDA’s provisional approval, the two parties entered into a settlement agreement where Hoechst would pay Andrx \$10 million every quarter until the patent litigation concluded, and Andrx would delay marketing any bioequivalent of Cardizem. *Id.* After the thirty-month stay elapsed, the FDA provisional approval was finalized, and Andrx was free to market its drug. *Id.* But Andrx chose not to market the drug and took the \$10 million quarterly payments. *Id.* Furthering the anticompetitive effect was Andrx’s 180-day exclusivity period; because the exclusivity period began when Andrx started marketing its drug, other potential generics marketers were prevented from marketing other bioequivalents of Cardizem. *Id.*

160. *See discussion supra* note 50.

The *Cardizem* court focused much of its analysis on this “parking” of Andrx’s generic exclusivity period, which essentially prevented other generic manufacturers from marketing Cardizem bioequivalents, extending the settlement agreement to cover potentially noninfringing products.¹⁶¹ The court analyzed the agreement as a whole, rather than decrying the monetary payment from plaintiff to defendant as per se illegal.¹⁶²

Some commentators have used the court’s holistic analysis to assert that it is somewhat unclear whether the Sixth Circuit would treat all reverse-payment settlements as per se illegal or if the presence of the generic exclusivity holds would be necessary to trigger per se illegality.¹⁶³ While the issue presented by generic exclusivity parking enhances the net anticompetitive effect of reverse-payment settlements, it is the *allocation* of the entire US market to the patent holder that triggers per se illegality. Therefore, regardless of the term requiring the generic manufacturer to refrain from exercising its 180-day exclusivity period, the Sixth Circuit could (and likely would) have found the agreement per se illegal.

B. Reverse-Payment Settlements as Agreements that Presumptively Reduce Competition

Even if reverse-payment settlements are not appropriately categorized as market allocation—and are therefore not per se illegal—they are likely still unreasonable restraints on trade under the rule of reason analysis. The Sherman Act provides that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”¹⁶⁴ Though the language is broad, courts have construed the Sherman Act to prohibit only *unreasonable* restraints of trade, including per se violations such as market allocations (which are presumptively unreasonable restraints of trade), but also non-per se transactions that are restraints of trade that lack sufficiently procompetitive justifications.¹⁶⁵

The unreasonableness of a trade restraint is determined by applying the “rule of reason.”¹⁶⁶ The rule of reason is not a set standard of behavior, but a broad-spectrum analysis into whether the

161. *In re Cardizem*, 332 F.3d at 907–09.

162. *Id.*

163. See Christopher M. Holman, *Do Reverse Payment Settlements Violate the Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489, 573 (2007).

164. 15 U.S.C. § 1 (2006).

165. See *State Oil Co. v. Khan*, 522 U.S. 3, 10–12 (1997).

166. See *id.*

challenged restraint “impos[es] an unreasonable restraint on competition” under “all . . . the circumstances.”¹⁶⁷ The inquiry includes balancing anticompetitive effects of the challenged restraint as proven by the plaintiffs against the procompetitive effects of the challenged restraint as proven by the defendant.¹⁶⁸ The plaintiff also has the opportunity to prove that the procompetitive effects advanced by the defendant are not sufficiently connected to the restraint itself, specifically by showing that the restraint is not the least restrictive means of obtaining the procompetitive benefit.¹⁶⁹

A traditional rule of reason analysis is ultimately an unserviceable venture when reviewing reverse-payment settlements involving large payments to a generic manufacturer in exchange for total exclusion from the patent’s market, because anticompetitive harm is almost certain in these cases.¹⁷⁰ A patentee—the pioneer who likely spent hundreds of millions of dollars¹⁷¹ in researching and developing the patented drug—naturally has little incentive to share what it rightfully owns. The fact that the patentee is making a substantial payment to the charged infringer suggests that there is uncertainty regarding either the validity of the patent or whether the charged infringer’s product actually infringes on the patent; if the patentee is confident in his right to exclude, the exclusion payment should not exceed the patentee’s expected costs of litigation.¹⁷² These large exclusion payments seem to exceed potential litigation costs, however, particularly when settlement amounts exceed tens of millions of dollars.¹⁷³ Therefore, it is reasonable to assume that the payments are anticompetitive because there was a significant enough chance that the generic brand actually did have a right to compete, thereby decreasing potential drug costs to retailers and consumers. For this reason, a substantial exclusion payment in a patent infringement settlement at least should be considered *prima facie*

167. *Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977) (“[T]he factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.”).

168. ABA ANTITRUST SECTION, MONOGRAPH NO. 23, THE RULE OF REASON 124–26 (1999).

169. *Id.* at 121–22.

170. *See* Hemphill, *supra* note 5, at 1568–73.

171. *See* DiMasi et al., *supra* note 34, at 180 (“Including an estimate of the cost per approved new drug for R&D conducted after approval increases total R&D cost to nearly US\$ 900 million.”).

172. *See* Shapiro, *supra* note 14, at 408.

173. *See, e.g., In re K-Dur Antitrust Litig.*, 686 F.3d 197, 205–06 (3d Cir. 2012) (disputing the settlement payment of \$60 million); *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1305 (11th Cir. 2012) (detailing the settlement payment of \$10 million per year for six years, plus profit share estimated at \$19–30 million per year), *cert. granted*, 133 S. Ct. 787 (2012); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 903 (6th Cir. 2003) (discussing a settlement payment of \$89.83 million).

evidence of anticompetitive harm with no requirement to establish further anticompetitive harm. The reasoning above justifies a strong presumption (as opposed to *prima facie* evidence) of anticompetitive harm, whereby defendants must provide compelling evidence of significant procompetitive effects arising from the payment.

The pharmaceutical defendants in the reverse-payment settlement cases discussed above all argued (1) the nature of the settlements are not anticompetitive, (2) the patentee has the right to enforce its patents through litigation and settlement, and (3) judicial policy should favor settlements.¹⁷⁴ Some commentators have also argued, however, that reverse-payment settlements might have further procompetitive effects by allowing early entry of generic brands into the market, as is often part of the settlement terms.¹⁷⁵ But early marketing of a generic drug can be achieved through much less restrictive means than a reverse-payment settlement ensuing from a patent infringement suit. In fact, if the patentee granted a licensing agreement, either within or outside of a settlement agreement, the effect would actually be procompetitive, assuming the licensing fees are not so exorbitant that the licensing agreement forces the licensee to keep prices high.¹⁷⁶

The Third Circuit's recent decision in *K-Dur* was based on presumptive illegality under the rule of reason analysis rather than *per se* illegality.¹⁷⁷ In applying the quick-look rule of reason analysis, rather than requiring the plaintiff to make a full-blown showing of the agreements' anticompetitive effects, the court presumed that reverse-payment settlements are unreasonable restraints on trade and shifted the burden to the defendant to show procompetitive justifications.¹⁷⁸ By establishing this presumption, there is no need to consider the merits of the underlying patent; the burden shifts directly to the defendant to show a purpose other than delayed entry or to offer a procompetitive benefit.

In rejecting the scope of the patent test and instead making a quick-look rule of reason analysis, the Third Circuit explained that it was "embrac[ing the Andrx] court's common sense conclusion that '[a] payment flowing from the innovator to the challenging generic firm

174. See, e.g., Brief for Respondent Solvay Pharm., Inc. at 16–29, *Watson Pharm.*, No. 12-416 (U.S. Nov. 13, 2012), 2012 WL 5507198; Brief of Appellees in Nos. 10-2077, 10-2078, 10-2079 and Appellants in No. 10-4571 at 33–35, *In re K-Dur*, 686 F.3d 197 (Nos. 10-2077, 10-2078, 10-2079, 10-4571), 2011 WL 2603658.

175. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 249–50 (E.D.N.Y. 2003).

176. See Holman, *supra* note 163, at 498–99.

177. See *In re K-Dur*, 686 F.3d at 217–18.

178. See *id.* at 218.

may suggest strongly the anticompetitive intent of the parties entering the agreement”¹⁷⁹ The court further asserted that it agreed with the FTC that there was no need to consider the merits of the underlying patent suit because “[a]bsent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.”¹⁸⁰

The presumption of unreasonableness is further bolstered by the difficult burden placed on the defendant to rebut the presumption.¹⁸¹ Because a defendant must prove that the payments were made in return for something other than delay of entry and because the payments are usually substantial, the defendant is not likely to meet this burden without actual significant concessions from the generic manufacturer.¹⁸² Additionally, these other concessions must also pass antitrust muster.¹⁸³ The defendant may alternatively show that the agreement actually increases competition, but the court expressly noted that this is “probably rare.”¹⁸⁴ The extraordinary difficulty that a defendant faces in rebutting the presumption creates a rule that will almost always have the same outcome as if the court adopted the Sixth Circuit’s *per se* treatment.

The Third Circuit’s decision did not directly address an important part of the Supreme Court’s quick-look standard, which requires that the quick look is appropriate only when “an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.”¹⁸⁵ But an observer with a basic understanding of economics could likely deduce that less competition, especially where a *de facto* economic monopoly is involved, would reasonably cause prices to increase. Though commentators have argued that these settlements could ultimately have some competitive benefits by allowing earlier entry into the market, the standard does not call for an understanding of countervailing procompetitive effects.¹⁸⁶ It requires only that an observer could reasonably conclude

179. *Id.* (quoting *Andrx Pharm., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 809 (D.C. Cir. 2001)).

180. *Id.* (quoting *In re Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003) (internal quotation marks omitted), *vacated*, 402 F.3d 1056 (11th Cir. 2005)).

181. *See id.*

182. *See id.*

183. *See id.*

184. *Id.*

185. *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770 (1999).

186. *See id.*

that there would be an anticompetitive effect.¹⁸⁷ Therefore, the Third Circuit's application of the quick-look rule was not inappropriate.

C. The Improper Development and Application of the Scope of the Patent Test

The concept of "scope" has been warped since *Cardizem*, albeit slowly and subtly. The scope of the patent framework was first established in *Cardizem*, in which the Sixth Circuit invalidated the challenged agreement because it restrained activities beyond the scope of the patent.¹⁸⁸ The court left open the question of whether a patent allows reverse-payment agreements encompassing only products and activities covered by the patent through reverse payments.¹⁸⁹

But just because a settlement that reaches a product outside the scope of the patent violates antitrust laws does not necessarily mean that one falling within the facial scope of the patent is automatically valid. The Second, Eleventh, and Federal Circuits took the framework established in *Cardizem*, meant to be applied to easy and blatant cases, and used the scope of the patent test to make the harder cases less fuzzy by changing the test to mean that any agreement that does not involve products outside the patent scope must be legal.¹⁹⁰ This is an example of inverse error in logic, a fallacy of propositional logic in which the negative of a true assumption is incorrectly used to infer the negative of a true conclusion.¹⁹¹

Furthermore, the application of the warped *Cardizem* test requires that the court assume the validity of the patent.¹⁹² While each court using the test denies that it is passing judgment on the validity of the patent in question, the court *must* assume validity in order to actually apply the test; if the patent is invalid, there is no patent scope to consider.¹⁹³ To apply the test, the court assumes that mere issuance of a patent evinces patent validity.¹⁹⁴ But empirical studies have consistently shown that at least 40 percent of granted

187. *See id.*

188. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908–09 (6th Cir. 2003).

189. *See id.*

190. *See, e.g., FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir.), *cert. granted*, 133 S. Ct. 787 (2012).

191. Gary N. Curtis, *Denying the Antecedent*, FALLACY FILES, <http://www.fallacyfiles.org/denyante.html> (last visited Dec. 31, 2012).

192. *See* Hemphill, *supra* note 5, at 1602 n.181.

193. *See id.* at 1560 (explaining that the value lies in determining the validity and scope of the patent).

194. *Id.* at 1602 n.181.

patents that are litigated to decision are declared invalid.¹⁹⁵ The rate of invalidity may be significantly higher in pharmaceutical patents, as an FTC study found that, between 1992 and 2000, generics prevailed in 73 percent of patent challenges.¹⁹⁶

Finally, the scope of the patent test is inappropriate because it misapplies general infringement burden-of-proof principles.¹⁹⁷ A patent serves as a shield rather than a sword for a patentee, and thus the patentee has the ultimate burden to prove infringement in order to exclude a competitor from marketing a challenged product.¹⁹⁸ By allowing the patentee to bypass its burden of proof by paying off a challenger, the patent becomes a sword, generating profits that the patentee may use to maintain an improper monopoly on a particular market.¹⁹⁹

D. The Insufficiency of Asserted Policy and Regulatory Justifications for the Scope of the Patent Test

Each of the courts applying the scope of the patent test has defended its application by referring to at least one of the following justifications. The first and most common justification is the judicial preference for settlement over litigation.²⁰⁰ Courts have noted that the “efficiency-enhancing” objectives should be considered, and “[p]ublic policy strongly favors settlement of disputes without litigation.”²⁰¹ For example, in *Schering-Plough*, the court expressed

195. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998) (showing that courts invalidated 46 percent of patents between 1989 and 1996); Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 385 (2000) (showing that challenged infringers prevailed in 42 percent of patent cases that reached trial between 1983 and 1999). But see Paul M. Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 33 n.61 (2006) (suggesting that infringer win rates are lower in more patent-heavy districts).

196. FED. TRADE COMM’N, *supra* note 15, at 16.

197. *Key Mfg. Grp., Inc. v. Microdot, Inc.*, 925 F.2d 1444, 1447 (Fed. Cir. 1991) (stating that “the [patentee] must show the presence” of infringing activity before an invalidity defense is needed (citing *Key Mfg. Grp., Inc. v. Microdot, Inc.*, 854 F.2d 1328 (Fed. Cir. 1988))); see also Hemphill, *supra* note 5, at 1602 n.181 (stating that the Patent Act “has been interpreted . . . to require that an invalidity defense . . . be established by clear and convincing evidence, rather than a mere preponderance”).

198. See *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed. Cir. 2008) (“[T]he patentee bears the ultimate burden of proof to demonstrate infringement by a preponderance of the evidence.”); see also discussion *supra* note 149.

199. See discussion *supra* note 148.

200. See *supra* notes 101, 127 and accompanying text.

201. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072–73 (11th Cir. 2005) (quoting *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976)) (internal quotation marks omitted) (citation omitted).

concern about the costs of litigation and overcrowded dockets.²⁰² Commentators have argued that the complex and technical nature of patent infringement litigation may further compound the reflexive preference toward settlement.²⁰³

Courts have also expressed concern that establishing a restrictive settlement rule could potentially reduce innovators' incentives to research and develop new drugs. In *Ciprofloxacin*, the court emphasized that a restrictive settlement rule could prevent beneficial settlements²⁰⁴ and undermine the innovator's incentives for research, thereby harming consumers.²⁰⁵ Furthermore, Judge Posner's argument in dicta in *Asahi Glass Co. v. Pentech Pharm., Inc.* has influenced the reverse-payment debate: "A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement"²⁰⁶ Thus, Judge Posner suggests that limiting settlement options would not only reduce the innovator's incentives, but also reduce a potential challenger's incentive to both innovate and challenge.²⁰⁷

Finally, courts have asserted that reverse-payment settlements are rational byproducts of the Hatch-Waxman Act because the regulatory scheme altered both the innovators' and generic challengers' incentives.²⁰⁸ Particularly, the court emphasizes that the generic challenger faces little risk for potentially great rewards because there is an incentive shift.²⁰⁹ The Act allows the generic manufacturer to infringe on the patentee's patent via certification.²¹⁰ Should the challenger lose in court, its loss is minimized to ANDA

202. *Id.* at 1076.

203. *See* Hemphill, *supra* note 5, at 1574; *see also* Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1308 n.20 (11th Cir. 2003) ("The cost and complexity of most patent litigation is a familiar problem to the court system.").

204. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005).

205. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003).

206. *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation).

207. *Id.*

208. The Eleventh Circuit noted:

Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generic manufacturers] gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits. This statutory scheme could then cost [the innovator patentee] its patent.

Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1074 (11th Cir. 2005) (citation omitted).

209. *See id.*

210. *See id.*

application costs and litigation costs.²¹¹ In *Schering-Plough*, the court again quoted Judge Posner in *Asahi*: "If any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements."²¹²

While there are certainly efficiency and incentive scheme benefits to consider, these considerations should not automatically override antitrust concerns arising from reverse-payment settlements.²¹³ Pharmaceutical patents are rare exceptions within the patent world because they provide not only an exclusionary legal monopoly (as every patent provides to its patentee), but also a de facto economic monopoly in which the patentee has a "significant market power."²¹⁴ The risk of antitrust abuse that accompanies an economic monopoly establishes further justification for courts to more carefully consider antitrust concerns in reverse-payment settlements of pharmaceutical patent infringement suits.

Furthermore, while it is true that reverse payments are *rational* byproducts of the Hatch-Waxman Act via shifting incentives, it should not directly follow that such payments are *legal* byproducts.²¹⁵ For example, the regulatory scheme governing public utilities, government contracting, and gasoline distribution provides natural incentives for participating firms to engage in price fixing.²¹⁶ However, should the firms engage in price fixing within the established regulatory scheme, surely courts should not excuse the per se illegal activity simply because the regulatory scheme provides incentives to engage in those activities.²¹⁷

211. See *id.*

212. *Id.* (quoting *Asahi Glass Co.*, 289 F. Supp. 2d at 994).

213. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 217 (3d Cir. 2012).

214. Where a firm has economic monopoly power, the firm is able to "price a product above marginal cost without losing substantial sales." NARD, *supra* note 148, at 667. Patents generally do not confer economic monopoly power because "there are usually viable substitutes for the patented good." *Id.* at 618. The availability of substitutes creates additional competition that applies pressure to a patent holder's pricing scheme, giving market incentives to price according to the value of the innovation. *Id.* at 673. Consider pharmaceuticals, however, where each new innovation has the potential to create a new market unto itself, thereby allowing a patent to confer both legal and economic monopolies. *Id.* at 674-75.

215. Hovenkamp et al., *supra* note 50, at 1758.

216. See Hemphill, *supra* note 5, at 1577-78.

217. See *id.*

III. THE LIKELY SOLUTION: JUDICIAL DETERMINATION OF THE DOMINANT THEORY OF LAW

The Supreme Court has a basic question to answer: which body of law trumps, patent or antitrust? The Court should answer this question in its review of *FTC v. Watson Pharmaceuticals*.²¹⁸ While the circuit courts have debated this and generally fallen on one side or the other, the best solution is one that recognizes the necessity for antitrust regulation in which a patent grant provides the patentee both a legal and economic monopoly. As such, judicial review of reverse-payment settlements should be bifurcated, using the scope of the patent to determine the demarcation between the different analyses: (1) any part of the agreement that *exceeds* the scope of the patent should be considered a per se illegal restraint on trade,²¹⁹ and (2) any part of the agreement that falls *within* the scope of the patent should be subject to rule of reason analysis, with a rebuttable presumption of restraint of trade when anything of value exchanged between the patentee and challenger exceeds potential costs of litigation.

Per se treatment of agreement terms falling outside of the scope of the patent is appropriate because such terms consistently have anticompetitive effects by prolonging the period of higher drug prices. Regardless of whether the patentee or the challenger benefits from the extension, the results will be the same: consumers will suffer.²²⁰

For the parts of the agreement that fall *within* the scope of the patent, such terms should be subject to rule of reason analysis, with a rebuttable presumption of restraint of trade when anything of value exchanged between the patentee and challenger exceeds potential costs of litigation. This test is the most appropriate because it recognizes that terms falling within the scope of the patent should be open to use in negotiations by the patent holder. But such uses must be limited in cases in which the patent holder also has complete

218. *FTC v. Watson Pharm., Inc.*, 133 S. Ct. 787 (2012).

219. When this Note refers to terms falling *outside* of the scope of the patent, it is referring to the relatively small subset of terms that effectively extends the legal monopoly period for *any* patented product. For example, if in exchange for large cash payments, the challenger not only agrees to delay entry into the market for the challenged product, but also agrees not to enter the market for related products (or gives exclusive rights to the patentee for other drugs that may have been able to compete with other patents), the net effect will be that competition is lowered in each relevant market. While it is true that restraint of trade may not actually be the overriding reason for each of these agreements, the fact that such agreements could be made under less suspicious circumstances, where there is an arguably better chance at negotiating a fair deal, necessarily taints the agreement.

220. See FED. TRADE COMM'N, *supra* note 2, at 1–2.

monopoly power. This test also gives the parties an opportunity to demonstrate that the net effect of the agreement is procompetitive.²²¹ It is important to note, however, that this test is applicable *only* where the patent grants the patent holder a de facto economic monopoly.

The scope of the patent test utilized by a majority of the federal circuit courts is untenable.²²² The test originates from a logical fallacy and ultimately an incorrect interpretation of the central ruling in *Cardizem*, requires a presumption of patent validity, and misapplies the burden of proof standards for infringement cases.²²³ Furthermore, the policy and regulatory concerns relied upon to justify the test do not override the need for antitrust review, particularly due to the special nature of pharmaceutical patents.²²⁴

IV. THE BETTER SOLUTION: LEGISLATIVE ACTION TO PATCH THE HATCH-WAXMAN LOOPHOLES

Congress is better situated to completely and decidedly address the problems arising from the Hatch-Waxman Act. Although members of Congress have made multiple attempts to amend the Hatch-Waxman Act to address the growing concern over reverse-payment settlements, each attempt thus far has failed.²²⁵ Bill supporters and the FDA agree that congressional resolution is the most appropriate measure to cure the unintended anticompetitive effects of the Hatch-Waxman Act.²²⁶ Throughout each attempt, the amendments have remained nearly identical²²⁷ and generally follow the recommendations made by the FTC.

The crucial change within each of the proposed bills is that the ANDA filer is prohibited from receiving “anything of value” in a patent

221. For a fuller discussion, see *supra* Part II.B.

222. See *supra* Part II.C.

223. See *supra* Part II.C.

224. See Hemphill, *supra* note 5, at 1597–604, for his discussion on the uneasy grounds for patent exceptionalism in pharmaceutical patents.

225. See *supra* Part I.D.

226. See, e.g., *The Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Commerce, Trade, & Consumer Prot. of the H. Comm. on Energy & Commerce*, 111th Cong. 189 (2009) [hereinafter *Hearing on H.R. 1706*] (statement of Joanne Handy, Board Member, AARP) (quoting Congressman Hatch, one of the original authors of the Act, that he “find[s] these types of reverse payment collusive agreements appalling” because Congress “did not wish to encourage situations where payments were made to generic firms not to sell generic drugs”); FED. TRADE COMM’N, *supra* note 15, at ii–xi (describing five legislative amendments to address the provisions allowing abusive reverse-payment settlements in the current version of the Hatch-Waxman Act).

227. See *Protecting Consumer Access to Generic Drugs Act of 2012*, H.R. 3995, 112th Cong. (2012); *Protecting Consumer Access to Generic Drugs Act of 2009*, H.R. 1706, 111th Cong. (2009); *Protecting Consumer Access to Generic Drugs Act of 2007*, H.R. 1902, 110th Cong. (2007).

infringement settlement agreement for the patent related to the filer's particular ANDA drug.²²⁸ This is the most critical amendment that must be made to prevent reverse-payment settlements. Such an amendment would effectively preclude the patentee and generic manufacturer from engaging in a reverse-payment transaction, because such payments would be "something of value." Critics of the amendment claim that such a restriction is too broad and would cover almost "any settlement agreement because a generic challenger logically would only settle in exchange for something of value."²²⁹ But such broad language is necessary to prevent payments disguised as ancillary deals without direct monetary value, which would otherwise allow continued exploitation of the loophole that the amendment seeks to repair.²³⁰

Congress should also alter the 180-day exclusivity period granted to the first ANDA filer.²³¹ This provision allows the ANDA filer to "park" its exclusivity rights, preventing other generic manufacturers from entering the market.²³² Section 4 of the proposed legislation would force the ANDA filer and exclusivity-rights holder to relinquish those rights should they enter into a prohibited settlement agreement, including those that involve reverse payments.²³³ A better solution would be to allow successive ANDA filers to "wait in line" to use the exclusivity period. If the first filer foregoes taking advantage of the exclusivity period by accepting a substantial payment or favorable licensing agreement from the patent holder, the next ANDA filer should be given the opportunity to also challenge the patent through the ANDA process. This would shift the incentives in the patent infringement litigation brought by pharmaceutical patent holders against ANDA filers, because the patent holder would know that settling with one filer will only lead to a battle with the next filer. By allowing successive ANDA filers to challenge the patent until the first filer utilizes the exclusivity period, the patent holder will be prevented from thwarting judicial testing of its patent's validity.

Finally, each of the proposed bills expressly delegated the responsibility of reverse-payment settlement review to the FTC.²³⁴

228. *E.g.*, H.R. 3995 § 2(a)(1).

229. *Hearing on H.R. 1706*, *supra* note 226, at 206 (statement of Diane E. Bieri, Executive Vice President & General Counsel, Pharmaceutical Research and Manufacturers of America).

230. *See Hearings on H.R. 1706*, *supra* note 226, at 55 (statement of C. Scott Hemphill, Associate Professor, Columbia Law School).

231. *See* discussion *supra* Part I.A.

232. *See* discussion *supra* Part I.A.

233. H.R. 3995 § 4 (2012).

234. *Id.* § 2(c).

The amendment would subject reverse-payment settlements to per se treatment as an “unfair and deceptive act or practice and an unfair method of competition in or affecting interstate commerce prohibited under section 5 of the Federal Trade Commission Act,” thereby giving the FTC complete review and enforcement responsibilities for every such agreement.²³⁵ This is not a critical change, but such a change would be a decisive move against reverse-payment settlements. Given the consistent negative view the FTC has taken toward reverse-payment settlements, compelling FTC review would effectively end the use of reverse-payment settlements.

These amendments, while imperfect, are the simplest and cleanest way to reestablish the regulatory scheme intended by the original passage of the Hatch-Waxman Act. It closes the two main loopholes that have caused the shift in incentives leading to the rise of the reverse-payment settlement. By disallowing receipt of value for intentional market-entry delay and requiring disgorgement of exclusivity rights should such an agreement be made, the proposed amendment would shift the incentives toward challenging weak patents or settlement on terms advantageous to each party without undue expense to the end consumer.

Still, Congress has attempted and failed three times to amend the Act to close the loopholes.²³⁶ But there is hope on the horizon for another push to recalibrate the law. With the impending Supreme Court review of *FTC v. Watson Pharmaceuticals*, Congress should seek to preempt judicial interference to prevent potential judicial warping of the purpose and effects of the Hatch-Waxman Act as Congress originally intended. Furthermore, with the rampant increases in health care costs and the political quagmire arising from the newly passed Patient Protection and Affordable Care Act, Congress has further incentives to reduce any additional cost to consumers. Finally, with the heightened concern over federal budget expenditures, the savings the federal government can expect by passing the legislation may become a more prominent factor in the bill's passage.²³⁷

235. *Id.*

236. See H.R. 3995; Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009); Protecting Consumer Access to Generic Drugs Act of 2007, H.R. 1902, 110th Cong. (2007).

237. This Note assumes that the federal government stands to gain in Medicare and Medicaid expenditures with the increased availability of generic-brand medicines.

V. CONCLUSION

With *FTC v. Watson Pharmaceuticals* slated to be decided by June 2013, Congress has enough incentive to give due consideration to a new proposal to amend the Hatch-Waxman Act. Congressional correction of a congressional mistake would provide for a much more stable solution to the reverse-payment phenomenon. Instead of having to review patent rights through an antitrust lens (or antitrust principles within the patent paradigm), legislation can simply create a bright line rule without making the difficult decision of which set of principles trumps the other. Furthermore, even given the past failures to push any such legislation beyond committee review, the time is ripe for Congress to take action because of the impending Supreme Court review and the current political and fiscal environment.

However, if Congress remains silent and does not pass legislation closing the Hatch-Waxman loopholes, the Supreme Court is poised to fill the void in its review of *FTC v. Watson Pharmaceuticals*. The Court should adopt the per se illegality treatment for any portion of an agreement that extends beyond the scope of the patent. For agreements that do not extend beyond the scope of the patent, where anything of value is passed from plaintiff to defendant in settling a pharmaceutical patent infringement suit, and such value exceeds the cost of litigating the suit to a final judgment, such payments should be prima facie evidence of an unreasonable restraint of trade.

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